510(k) Number: K041496

510(k) SUMMARY

(As Required by 21 CFR 807. 92)

JUN 3 0 2005

Submitted by:	**Dr. Vittorio Servidori** General Manager PENTAFERTE S.p.A Loc. Nocella Statale 262 64012 Campli (Teramo), Italy Tel: 011 39 0532 778811 Fax: 011 39 0532 778812
Date of Summary:	April 10, 2003
Device Name:	PENTATRASFU™ Blood Transfusion Sets
Common Name:	Blood Transfusion Set
Classification Name:	Set, Blood Transfusion
Class:	2
Product Code:	BRZ
Regulation Number:	21 CFR 880. 5440
Predicative Device:	Tuta Healthcare Blood/Solution Administration Sets (K023039) Baxter Healthcare Blood Transfusion Set (K924721)
Modifications:	There are no modifications to the device design that affect safety and effectiveness of the PENTATRASFU™ Blood Transfusion Sets.

K041496

SAFETY AND EFFICACY FOR PENTATRASFU™ BLOOD TRANSFUSION SETS

SUMMARY

(As Required by 21 CFR 807. 92)

Can Substantially Equivalence be established between the PENTATRASFU™ Blood Transfusion Sets and the Predicative devices?

Yes, the PENTATRASFU™ Blood Transfusion Sets are substantially equivalent to the predicative devices based on the following criteria:

a. These Blood Transfusion Sets are used to administer blood from a container (plastic bag or glass bottle) to a patient's vascular system through a needle or Catheter inserted into a vein, same as the predicative devices.

b. These Blood Transfusion Sets and the predicative devices have the same Instructions for Use: To ***administer Blood into a patient's vascular system***.

c. These Blood Transfusion Sets are manufactured with similar biocompatible materials as the predicative devices. PVC tubing, Polyethylene, White PVC, and Natural Rubber. Biocompatibility testing of these Blood Transfusion Sets showed the materials to be biocompatible for their intended use.

d. These Blood Transfusion Sets have similar design and the same principle of operation as the Predicative Blood/Solution Administration Sets.

e. These blood Transfusion Sets do not have new or different characteristics that those of the Predicative devices, and the descriptive characteristics of this Blood Transfusion Sets are sufficient to ensure equivalence to the Predicative devices.

f. These Blood Transfusion Sets have been tested for performance as per recognized Standard Guidance Document ISO 1135-4 Second Edition 1998-03-15 Transfusion Equipment for Medical Use – Part 4 Transfusion Sets for Single Use (General Plastic Surgery/Gen, Hospital), which is the same standard that applies to the Predicative devices. The results of the Performance Testing showed that these Blood Transfusion Sets met the testing requirements as described on the ISO 1135-4 Recognized Guidance Document.

g. Biocompatibility testing conforms to FDA recognized standard 10993.

K041496

Device Description	The PENTATRASFU™ Blood Transfusion Sets are Single Use, Non-toxic, Sterile, Non-Pyrogenic devices used to administer Blood to a patient's vascular system through a Needle or Catheter inserted into a vein.
Intended Use:	To Administer Blood to the patient's vascular system.
Technological	The PENTATRASFU™ blood Transfusion Sets have the same technological characteristics as the legally marketed predicative Blood Transfusion Sets.
Testing:	The PENTATRASFU™ blood Transfusion Sets have been subjected to performance and safety testing to verify mechanical properties and functioning, as well as biocompatibility and sterility, using FDA recognized Standards, where applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2005

Pentaferte S.P.A
C/O Mr. Victor Pereira
Consultant
Pentaferte S.P.A
7240 NW 63 Terrace
Parkland, Florida 33067

Re: K041496
Trade/Device Name: PENTATRASFU™ Blood Transfusion Sets
Regulation Number: 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: BRZ
Dated: May 31, 2005
Received: June 15, 2005

Dear Mr. Pereira:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number K041496

Device Name: PENTATRASFU™ Blood Transfusion Sets

INDICATIONS FOR USE: To administer Blood and Blood Derivatives into a patient's vascular system

Prescription Use ✓ **AND/OR** **Over- The Counter Use:** ____
(21CFR 801 Subpart D) **(21 CFR Subpart C)**

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K041496